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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,049	01/22/2004	Harriet L. Robinson	07917-217002	3662
26161	7590	06/02/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			LONG, SCOTT	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/763,049	Applicant(s) ROBINSON ET AL.	
	Examiner Scott D. Long	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Species Elections

Two different species elections are required for the DNA vaccine invention: (1) Viral Source of Antigens and (2) Administration Route.

SPECIES 1 ELECTION: Viral Source of Antigens

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of Antigen Source (1-4) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-5, 16-19, 24, 32, 34-36, 44-49, and 52-53 are generic to species of Viral Sources of Antigens.

The Antigen Source species are independent or distinct. The antigens encoded by the DNA transcription units of the instant invention are derived from several types of viruses. Each of these viruses has unique protein structures that differ from the proteins of the other viruses. Different proteins having different amino acid sequences are structurally distinct chemical compounds and are unrelated to one another. Because each virus provides a unique pool of potential antigens which are structurally distinct from those of another virus, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search

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and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

Therefore, election is required of one of the inventive groups (1-4), regarding a viral antigen source, specifically:

- 1) Influenza virus, as recited in claims 6-7, 25-26, 54-56
- 2) Rotavirus, as recited in claims 8, 27;
- 3) Simian immunodeficiency virus, as recited in claim 9, 28, 40,50;
- 4) Human immunodeficiency virus, as recited in claim 10, 29, 41,51;

SPECIES 2 ELECTION: Administration Route

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of Administration Route (a-f) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-5, 16-19, 24, 32, 34-36, 44-49, 52-53 are generic to species of Administration Routes.

The Administration Route species are independent or distinct. Each of the Administration routes has distinct pharmacological characteristics that determine the degree of tissue diffusion, rate of dispersal, degree of absorption. For example intradermal drugs diffuse slowly from the injection site into local capillaries, and the process is a little faster with drugs administered subcutaneously. Furthermore, due to the rich supply of blood to muscles, absorption following an intramuscular injection is

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even quicker. Rectal and sublingual absorption is usually rapid due to the vascularity of the mucosa, for example. Further, absorption from instillation into the nose may lead to systemic as well as local effects, while inhalation into the lungs provides for extensive absorption.

Because each administration route has distinct characteristics that affect drug behavior and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

Therefore, election is required of one of the inventive groups (a-f), regarding Administration Route, specifically:

- a) Intravenous, as recited in claims 13, 33;
- b) Intramuscular, as recited in claims 13, 33;
- c) Intraperitoneal, as recited in claims 13, 33;
- d) Intradermal, as recited in claims 13, 33;
- e) Subcutaneous, as recited in claims 13, 33;
- f) Mucosa, as recited in claims 14, 20-22.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The distinctions between the species of each of the two elections are noted above. Because these species are structurally distinct and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction/species election for examination purposes as indicated is proper.

Response Requirement

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

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and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Multiple Inventors

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave Nguyen** can be reached on **571-272-0731**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long

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DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER